

MULTI-TIP STEERABLE CATHETER

5 CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/422,227, filed October 30, 2002, the entire disclosure of which is incorporated herein by reference.

10 BACKGROUND OF THE INVENTION

Electrophysiology catheters are commonly used for mapping electrical activity in a heart. By mapping the electrical activity in the heart, one can detect ectopic sites of electrical activation or other electrical activation pathways that contribute to heart malfunctions. This type of information may then allow a cardiologist to intervene and destroy the malfunctioning heart tissues. Such destruction of heart tissue is referred to as ablation, which is a rapidly growing field within electrophysiology and obviates the need for maximally invasive open heart surgery.

Such electrophysiology mapping catheters typically have an elongated flexible body with a distal end that carries one or more electrodes that are used to map or collect electrical information about the electrical activity in the heart. The distal end can be steerable or deflectable to assist the user in properly positioning the catheter for mapping in a desired location. However, often numerous electrical measurements must be taken to properly map the heart, which can be time consuming if the measurements are taken one at a time. Accordingly, a need exists for an improved catheter that can take multiple measurements simultaneously to make the mapping process more efficient.

SUMMARY OF THE INVENTION

30 The present invention is directed to an improved catheter for mapping the electrical activity in a heart. The catheter comprises a plurality of deflectable spines, each capable of obtaining electrical, mechanical and/or locational data. The use of a plurality of spines permits simultaneous mapping of multiple points, increasing the speed of mapping of regions of interest, e.g., the left and right ventricles.

5 In one embodiment, the invention is directed to a catheter comprising an elongated catheter body having a proximal end, a distal end and at least one lumen extending longitudinally therethrough. A control handle is attached to the proximal end of the catheter body. A mapping assembly is mounted at the distal end of the catheter body. The mapping assembly comprises at least two elongated flexible spines, each spine having a proximal end fixedly attached at or near the distal end of the catheter body and a free distal end. Each spine carries 10 at least one electrode along its length. The catheter further comprises at least two spine puller wires, each spine puller wire corresponding to one of the at least two spines. Each spine puller wire has a proximal end anchored in the handle and a distal end anchored at or near the distal end of its corresponding spine such that, in use, longitudinal movement of a spine puller wire relative to the 15 catheter body results in deflection of the spine in which the spine puller wire is anchored.

DESCRIPTION OF THE DRAWINGS

20 These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of a catheter according to the invention.

FIG. 2 is an end cross-sectional view of the catheter body of FIG. 1 taken along line 2-2.

25 FIG. 3 is an end cross-sectional view of a spine of the catheter of FIG. 1 taken along line 3-3.

FIG. 4 is a side cross-sectional view of the control handle of the catheter of FIG. 1.

30 DETAILED DESCRIPTION OF THE INVENTION

The invention is directed to a catheter having at its distal end a mapping assembly comprising a plurality of steerable or deflectable spines. Each spine carries one or more electrodes such that, when the spines are positioned in contact with heart tissue, each spine is capable of obtaining electrical data.

5 As shown in FIG. 1, the catheter comprises an elongated catheter body 12 having proximal and distal ends, a mapping assembly 13 comprising a plurality of spines 14 mounted at the distal end of the catheter body, and a control handle 16 at the proximal end of the catheter body.

10 As shown in FIGs. 1 and 2, the catheter body 12 comprises an elongated tubular construction having a single, axial or central lumen 15, but can optionally have multiple lumens along all or part of its length if desired. The catheter body 12 is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body 12 can be of any suitable construction and made of any suitable material. A presently preferred construction of the catheter body 12 comprises an outer wall 18 made of polyurethane or PEBA^X® (polyether block amide). The outer wall 18 preferably comprises an imbedded braided mesh of stainless steel or the like, as is generally known in the art, to increase torsional stiffness of the catheter body 12 so that, when the control handle 16 is rotated, the distal end of the catheter body 12 will rotate in a corresponding manner.

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20 A stiffening sleeve 19 is coaxially mounted in the lumen 15 of the catheter body 12 to provide improved torsional stability. The stiffening sleeve 19 preferably has an outer diameter that is slightly smaller than the inner diameter of the outer wall 18. The stiffening sleeve 19 is preferably made of polyimide or other suitable biocompatible plastic. If desired, the stiffening sleeve can be eliminated.

25 The length of the catheter body 12 is not critical, but preferably ranges from about 90 cm to about 120 cm, and more preferably is about 110 cm. The outer diameter of the catheter body 12 is also not critical, but is preferably no more than about 8 french, more preferably about 7 french. Likewise, the thickness of the outer wall 18 is not critical, but is preferably thin enough so that the central lumen 15 can accommodate all necessary wires and other components extending through the catheter body 12.

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35 In the depicted embodiment, the mapping assembly 13 comprises three spines 14. As will become apparent, the number of spines can vary as desired, and preferably ranges from two to twelve, more preferably from three to eight. Each spine 14 has a proximal end attached at the distal end of the catheter

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5 body **12** and a free distal end, i.e., the distal end is not attached to any of the other spines, to the catheter body, or to any other external structure that confines movement of the distal end. Each spine **14** comprises a plastic tubing made of any suitable biocompatible material, such as PEBA^X or polyurethane, having one or more lumens extending therethrough. Preferably each spine **14** comprises a multi-lumen, more preferably a dual-lumen, extrusion. In the depicted embodiment, each spine includes a lead wire lumen **26** and a puller wire lumen **27**, discussed further below. The puller wire lumen **27** is preferably off-axis. As would be recognized by one skilled in the art, the number, sizes and arrangement of the lumens can vary as desired. The lengths the spines will depend on the particular application for which the catheter is being used. Preferably each spine has a length ranging from about 0.5 cm to about 25 cm, more preferably from about 1 cm to about 10 cm, still more preferably from about 10 2 cm to about 7 cm.

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20 If desired, each spine **14** can have a preformed shape. This can be accomplished by including in each spine **14** a support arm (not shown)comprising a metal or plastic material that has shape memory, such as nitinol, so that the support arm forms an initial shape when no external forces are applied, forms a deflected shape when an external force is applied, and returns to its initial shape when the external force is released. Such a design is disclosed in U.S. Patent Application No. 10/231,875, entitled "Catheter and Method for Mapping Purkinje Fibers," the entire disclosure of which is incorporated herein by reference.

25 The spines **14** are connected to each other and to the distal end of the catheter body **12** at their proximal ends, as shown in FIG. 1. Preferably the proximal ends of the spines **14** are melted, glued or otherwise fused to each other and to the distal end of the catheter body **12** at a junction **24** to provided a unitary construction. Thus the spines **14** are permanently attached to the catheter body **12** and not retractable into the catheter body.

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35 In the depicted embodiment, the distal end of each spine **14** has an atraumatic tip comprising a polyurethane cap **22**. Each polyurethane cap is glued or otherwise fixedly attached to the distal end of its corresponding spine **14**. Other atraumatic tip designs could be used in connection with the invention.

5 As described in more detail below, the spines **14** are moveable between a deflected arrangement, wherein, for example, each spine extends outwardly from the catheter body **12**, or the spines **14** may be arranged in a collapsed arrangement, wherein, for example, each spine is disposed generally parallel to the longitudinal axis of the catheter body **12** so that the spines are capable of fitting within a lumen of a guiding sheath, as discussed further below.

10 Each spine **14** carries at least one electrode mounted along its length. In the depicted embodiment, five ring electrodes **28** are mounted, preferably evenly-spaced, on each spine **14**. As would be recognized by one skilled in the art, the number and arrangement of the electrodes on each spine can vary as desired. For example, one or more of the spines **14** could carry a tip electrode (not shown) on the distal end of the spine in place of the polyurethane cap **22**. Each ring electrode **28** has a length preferably up to about 2 mm, more preferably from about 0.5 mm to about 1 mm. The distance between the ring electrodes **28** preferably ranges from about 1 mm to about 10 mm, more preferably from about 15 2 mm to about 5 mm. Preferably each spine carries from 2 to about 20 electrodes, more preferably from 3 to 10 electrodes.

20 Each ring electrode **28** is electrically connected to an electrode lead wire **29**, which in turn is electrically connected to a connector **17** at the proximal end of the catheter. The connector **17** is connected to an appropriate mapping or monitoring system (not shown). Each electrode lead wire **29** extends from the connector **17**, through the control handle **16**, through the central lumen **15** in the catheter body **12**, and into the lead wire lumen **26** of the spine **14** where it is attached to its corresponding ring electrode **28**. Each lead wire **29**, which includes a non-conductive coating over almost all of its length, is attached to its corresponding ring electrode **28** by any suitable method.

25 A preferred method for attaching a lead wire **29** to a ring electrode **28** involves first making a small hole through the wall of the spine **14**. Such a hole can be created, for example, by inserting a needle through the wall of the spine **14** and heating the needle sufficiently to form a permanent hole. The lead wire **29** is then drawn through the hole by using a microhook or the like. The end of the lead wire **29** is then stripped of any coating and welded to the 30 underside of the ring electrode **28**, which is then slid into position over the hole 35

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5 and fixed in place with polyurethane glue or the like. Alternatively, each ring electrode **28** may be formed by wrapping the lead wire **29** around the spine **14** a number of times and stripping the lead wire of its own non-conductive coating on its outwardly facing surfaces. In such an instance, the lead wire **29** functions as a ring electrode.

10 Additionally, a mechanism is provided for individually deflecting or steering each of the spines **14**. Specifically, a spine puller wire **32** is provided for each spine **14**. Each spine puller wire **32** has a proximal end anchored to the control handle **16**, as described further below, and a distal end anchored at or near the distal end of its corresponding spine **14**. Each spine puller wire **32** extends through the puller wire lumen **27** of its corresponding spine and through the central lumen **15** of the catheter body **12**. Each spine puller wire **32** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like to impart lubricity to the puller wire. Each puller wire **32** preferably has a diameter ranging from about 0.006 to about 0.010 inches. Within each spine **14**, a plastic, preferably Teflon®, protective sleeve **33** is provided in surrounding relation to each puller wire **32** to prevent the puller wire from cutting through the wall of the spine during deflection.

15 A preferred mechanism for anchoring a spine puller wire **32** to its corresponding spine **14** comprises a T-bar anchor, as generally described in U.S. Patent Nos. 5,893,885 and 6,066,125, the entire disclosures of which are incorporated herein by reference. If a spine **14** carries a tip electrode, the spine puller wire **32** can be anchored in the tip electrode, as also described in U.S. Patent No. 6,066,125. Alternatively, a spine puller wire **32** can be attached to the side of the spine **14**, as generally described in U.S. Patent No. 6,123,699, the entire disclosure of which is incorporated herein by reference. Other arrangements for anchoring a spine puller wire to the distal end of a spine are included within the scope of the invention.

20 A compression coil **34** is situated within the catheter body **12** in surrounding relation to each spine puller wire **32**. Each compression coil **34** extends from the proximal end of the catheter body **12** to the junction **24** of the catheter body and mapping assembly **13**. Each compression coil **34** is made of any suitable metal, preferably stainless steel. Each compression coil **34** is tightly

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wound on itself to provide flexibility, i.e., bending, but to resist compression. The
5 inner diameter of each compression coil **34** is preferably slightly larger than the
diameter of its corresponding spine puller wire **32**. The Teflon® coatings on the
puller wires **32** allows them to slide freely within the compression coils **34**. If
desired, the outer surface of each compression coil **34** can be covered by a
flexible, non-conductive sheath (not shown), e.g., made of polyimide tubing, to
prevent contact between the compression coil **34** and the lead wires **29** within
10 the catheter body **12**.

A catheter puller wire **36** can also be provided for deflection of the distal
end of the catheter body **12** near the junction **24** of the catheter body and
mapping assembly **13**. With such a design, the catheter puller wire **36** is
anchored at its distal end to the outer wall **13** of the catheter body near the
15 junction **24**, as generally described in U.S. Patent No. 6,123,699, and is anchored
at its proximal end to the control handle **16**, as discussed further below. Within
the catheter body **12**, the catheter puller wire **36**, like the spine puller wires **32**,
extends through a compression coil **34**. If desired, the distal end of the catheter
body **12** can comprise a piece of tubing (not shown) that is more flexible than the
20 rest of the catheter body and that contains an off-axis lumen (not shown) into
which the distal end of the catheter puller wire **36** extends, as generally
described in U.S. Patent No. 6,123,699.

Longitudinal movement of a spine puller wire **32** relative to the catheter
body **12**, which results in deflection of the corresponding spine **14**, is
25 accomplished by suitable manipulation of the control handle **16**. Similarly,
longitudinal movement of the catheter puller wire **36** relative to the catheter
body **12**, which results in deflection of the distal end of the catheter body
proximal to the mapping assembly **13**, is accomplished by suitable manipulation
of the control handle.

As shown in FIGs. 1 and 4, a preferred control handle comprises a
30 generally cylindrical housing **40** having a piston chamber **42** at its distal end. A
generally cylindrical piston **44** is disposed within and generally coaxial with the
piston chamber **42**. The piston **44** includes a circumferential O-ring notch **46**
35 that carries an O-ring **48** to provide a snug, watertight fit between the piston and
the wall of the piston chamber **42**. The piston **44** has an axial bore **50** along its

length. The diameter of the axial bore **50** is approximately the same as the outer diameter of the catheter body **12**. The proximal end of the catheter body **12** 5 extends into the axial bore **50** and is fixedly attached, for example, by glue, to the piston **44**. The spine puller wires **32**, catheter puller wire **36**, and electrode lead wires **29** extend from the catheter body **12**, through the axial bore **50** of the piston **44** and into the control handle **16**.

10 The distal end of the piston **44** extends beyond the distal end of the housing **40** so that it can be manually controlled by the user. An annular thumb control **52** is attached at or near the distal end of the piston **44** to facilitate lengthwise movement of the piston relative to the housing **40**.

15 The proximal end of the catheter puller wire **36** is anchored to the housing **40** by any suitable method. In the depicted embodiment, the catheter puller wire **36** is anchored to the housing by means of an anchor **54** that extends into a transverse hole in the housing proximal to the piston chamber **42**. Such a design is described in more detail in U.S. Patent No. 5,383,923, the entire disclosure of which is incorporated herein by reference. In use, the distal end of the catheter body **12** can be curved or bent by moving the piston **44** distally out 20 of the piston chamber **42** by pushing outwardly on the thumb control **52**.

25 For longitudinal movement of the spine puller wires **32**, the housing includes three longitudinal slots **56**, preferably generally evenly-spaced about its circumference. A slider **58** is slidably mounted in each longitudinal slot **56**, as best shown in FIG. 1. The proximal end of each spine puller wire **32** is anchored to the portion of its corresponding slider **58** that is contained within the handle housing **40** by any suitable method. A suitable method for anchoring a spine puller wire **32** to a slider **58** involves a short stainless steel tubing **60** or the like 30 mounted on the proximal end of the puller wire. The slider **58** includes an opening **62** for receiving the stainless steel tubing **60** and a channel **64** distal to the opening having a size that permits a spine puller wire **32** to pass therethrough but that prevents the stainless steel tubing from passing therethrough. Other mechanisms for anchoring the spine puller wires **32** to the sliders **58** are within the scope of the invention.

35 Other control handles capable of manipulating a plurality of puller wires can also be used in connection with the invention. Examples of such handles are

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5 disclosed in U.S. Patent No. 6,066,125 and U.S. Patent Application No. 09/710,210, entitled "Deflectable Catheter with Modifiable Handle," the disclosures of which are incorporated herein by reference.

10 If desired, each spine **14** can also include one or more location sensors (not shown), such as an electromagnetic location sensor, for conveying locational information about the electrodes on the spine. Use and design of such location sensors are described in more detail in U.S. Application No. 10/040,932, entitled "Catheter Having Multiple Spines Each Having Electrical Mapping and Location Sensing Capabilities," the disclosure of which is incorporated herein by reference.

15 To use the catheter of the invention, a cardiologist or electrophysiologist introduces a guiding sheath and a dilator into the patient, as is generally known in the art, so that the distal ends of the sheath and dilator are in the region of the heart to be mapped. The dilator is removed from the guiding sheath, and the catheter is introduced into the patient through the guiding sheath. To insert the catheter into the guiding sheath, the mapping assembly **13** must be in its collapsed arrangement, wherein each spine **14** is disposed generally along the 20 longitudinal axis of the catheter body **12**. A suitable guiding sheath for use in connection with the catheter is the PREFACE™ Braided Guiding Sheath (commercially available from Biosense Webster, Inc., Diamond Bar, California). Such a guiding sheath has sufficient strength to hold each spine **124** in the collapsed arrangement, such that the spines and also the entire remainder of the 25 catheter can travel within the guiding sheath, from an insertion point in the patient, through a vein or artery and to a desired location in the heart.

30 Once the distal end of the catheter has reached the desired location, such as a position within the left ventricle of the heart, relative longitudinal movement between the catheter and the guiding sheath is provided to allow at least a portion, and preferably all, of each spine **14** to protrude from the guiding sheath. Preferably the guiding sheath is moved proximally relative to the distal end of the catheter to expose the spines **14**. When a spine **14** protrudes from the guiding sheath, the user can then use control handle to manipulate the corresponding spine puller wire **32** to deflect that spine so that it can be positioned in a desired region for mapping. Preferably at least one electrode 35

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5 from each spine **14** is placed into contact with a first plurality of the heart tissue such that electrical, and optionally locational and mechanical, information can be obtained from the contacted heart tissue. The spines **14** can then be further deflected or undeflected and/or repositioned to a second arrangement to contact a second plurality of heart tissue such that electrical, and optionally locational and mechanical, information can be obtained from these tissues as well.

10 After mapping is completed, the catheter is moved proximally relative to the guiding sheath to retract the spines within the sheath. During mapping, the region between the spines **14** can be prone to thrombus formation, which can make it difficult to withdraw the spines back into the sheath. To minimize such thrombus formation, irrigation fluid may be introduced through the catheter using an irrigation tube (not shown), as generally described in U.S. Patent Application No. 10/040,932, entitled "Catheter Having Multiple Spines Each Having Electrical Mapping and Location Sensing Capabilities."

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20 Using the inventive catheter having multiple spines, each having electrical and optionally mechanical mapping and locational sensing capabilities, the cardiologist can map local activation time and obtain voltage maps. The cardiologist can also determine those locations in the heart having no mechanical activity by monitoring whether the position of the location sensor changes over a complete cardiac cycle. This information can guide the cardiologist in providing therapy to the patient. For example, where the cardiologist finds regions of the heart that do not have mechanical activity, he or she can revascularize those regions using known techniques, such as gene therapy or transmyocardial revascularization. The inventive catheter allows the cardiologist to map the heart more quickly than traditional catheters by measuring multiple points of data at a time.

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30 The preceding description has been presented with references to presently preferred embodiments of the invention. Persons skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structures can be practiced without meaningfully departing from the principle, spirit and scope of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and shown in the accompanying drawings, but rather

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should be read as consistent with and as support for the following claims, which are to have their fullest and fairest scope.

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